K003945

FEB - 2 2001

510 (k) SUMMARY

I. GENERAL INFORMATION:

Establishment:

•Address: Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ. 08830

•Registration Number: 2240869

•Contact Person: Praveen Nadkarni
Technical Specialist, Regulatory Affairs
Telephone: (732) 321- 4950
TELEFAX: (908) 321 - 4841

Date of Summary Preparation:

Device Name:

•Trade Name: OPDIMA Digital Mammographic X-ray System

(Optimized Digital Mammography System)

•Common Name: Mammographic X-ray System

•Classification Name: Mammographic X-ray System-892.1710

•Classification: Class II

Performance Standards: 21 CFR, Subchapter J

All system components to which the above standard applies are certified to conform with 21 CFR subchapter J

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION.

Device Description:

The fully functional OPDIMA mammographic x-ray system configuration consists of the commercially available Mammomat 3000 mammographic x-ray system configured with OPDIMA option. The Mammomat 3000 with OPDIMA option is an Optimized Mammography System intended for use in small field digital mammographic examinations. The Mammomat

3000 with the OPDIMA option consists of the Mammomat 3000 stand and generator configured with a camera assembly, i.e., CCD detector, biopsy unit and a workstation for the display and processing of images, modem, MO drive, trolley, Biopsy controller and OPDIMA software (Application Software and Biopsy Controller software).

The user can select three modes of operation, Spot, biopsy or normal (non-digital) mode. The system is designed with key image processing functions, Zoomfactor, Magnifying Glass, Contrast Enhancement, Image invert, Histogram, Electronic ruler and image filter. Zoomfactor and Magnifying glass provide 2x, 4x and 8x magnification. For image filtering, five image filters are selectable. The Histogram feature displays the population for each grey scale value.

Intended Use:

The Siemens Mammomat 3000 with OPDIMA option is intended for use in small field mammographic x-ray imaging. Such small field imaging is used during stereotactic biopsy and diagnostic spot localization.

Technological Characteristics:

The OPDIMA mammographic X-ray system consists of the Mammomat 3000 configured with the OPDIMAOption . The major system components consist of the Mammomat 3000 X-ray stand and generator, CCD detector, biopsy unit, Biopsy controller, OPDIMA system software and workstation. The CCD detector has an imaging area of 49 x 85 mm. The pixel sizes vary according to the mode of operation; 24 µm in normal resolution mode and 48 µm high resolution mode. The pixel matrices are 2048 x 3584 pixel in normal resolution mode and 1024 x 1792 pixel in high resolution mode with a pixel depth of 12 bits. The image resolution is > 10 lp/mm in high resolution mode and > 13 lp/mm in normal resolution mode.

The OPDIMA workstation is a 32 bit, 140 Mhz processor with 64 MB RAM, 32 kB and 2GB hard disk. The monitor has a resolution of 1024 x 1280 with 8-bit pixel depth. The system is equipped 2GB hard disc for archiving of approximately 500 images and optional disc achiving of 2.6 GB (250 images in spot mode and 1000 images in biopsy mode) per additional disc.

General Safety and Effectiveness Concerns:

Instructions for use are included within the device labeling and the information provided will enable the trained healthcare professional to operate the device in a safe and efficacious manner. Furthermore the operators are health care professionals familiar with and responsible for the X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

Substantial Equivalence:

In the opinion of Siemens Medical Systems, Inc., the bench testing information and the clinical study data proves that OPDIMA is substantially equivalent for diagnostic spot imaging to a film/screen spot imaging device used in conjunction with the commercially available Mammomat 3000 mammographic x-ray system.

Kathleen Rutherford 12/20/00

Kathleen Rutherford **Date**
Manager, Regulatory Submissions

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Praveen Nadkarni
Siemens Medical Systems, Inc.
Technical Specialist, Regulatory Affairs
186 Wood Avenue South
ISELIN NJ 08830

Re: K003945
OPDIMA
Dated: December 20, 2000
Received: December 21, 2000
Regulatory Class: II
21 CFR §892.1710/Procode: 90 IZH

Dear Mr. Nadkami:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications for Use

510(k) Number (if known): _____

Device Name: OPDIMA (Optimized Digital Mammography System)

Indications For Use:

The Siemens OPDIMA System is a digital small field mammographic x-ray option for the commercially available Mammomat 3000 mammographic x-ray system. The Mammomat 3000 with OPDIMA option is intended for use in small field digital mammographic x-ray imaging. Such small field imaging is used during stereotactic biopsy, spot localization and diagostic spot imaging..

Prescription Use ✓
(Per 21 CFR 801.109)

David C. Segram

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003945